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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

GILEAD SCIENCES, INC., HOFFMANN-La ROCHE INC., F. HOFFMANN-La ROCHE LTD. and GENENTECH, INC., Plaintiffs, v. NATCO PHARMA LIMITED and NATCO PHARMA INC., Defendants.	C.A. No. 1:11-cv-01455-SDW-MCA Consolidated with C.A. No. 2:11-cv-04969-SDW-MCA

NATCO PHARMA LIMITED'S AND
NATCO PHARMA, INC.'S ANSWER AND COUNTERCLAIMS

Defendants Natco Pharma Limited ("Natco Ltd.") and Natco Pharma Inc. ("Natco Inc.") (collectively "Natco") hereby respond to the corresponding paragraphs of the Complaint of plaintiffs Gilead Sciences, Inc., Hoffman-La Roche Inc., F. Hoffman-La Roche Ltd. and Genentech, Inc. (collectively "Plaintiffs") as follows:

NATURE OF THE ACTION

1. Denied, except to admit that the Complaint purports to state a cause of action for infringement of United States Patent No. 5,763,483 ("the '483 Patent").

PARTIES

2. Natco is without sufficient knowledge to admit or deny the allegations in Paragraph 2 of the Complaint, and therefore denies the same, leaving Plaintiffs to their proofs.

3. Natco is without sufficient knowledge to admit or deny the allegations in Paragraph 3 of the Complaint, and therefore denies the same, leaving Plaintiffs to their proofs.

4. Natco is without sufficient knowledge to admit or deny the allegations in Paragraph 4 of the Complaint, and therefore denies the same, leaving Plaintiffs to their proofs.

5. Natco is without sufficient knowledge to admit or deny the allegations in Paragraph 5 of the Complaint, and therefore denies the same, leaving Plaintiffs to their proofs.

6. Admitted.

7. Admitted.

8. Denied, except to admit that Natco Ltd. does not contest personal jurisdiction within this judicial district for the limited purposes of this action with respect to the ‘483 Patent.

9. Admitted.

10. Denied, except to admit that Natco Inc. is a wholly owned subsidiary of Natco Ltd.

11. Admitted.

12. Denied.

13. Denied, except to admit that Natco Inc. does not contest personal jurisdiction within this judicial district for the limited purposes of this action with respect to the ‘483 Patent.

JURISDICTION AND VENUE

14. Admitted.

15. Denied, except to admit that Natco has a website at http://www.natcopharma.co.in/index.html, which includes the following statement: "NATCO PHARMA was promoted by Mr. V.C. Nannapaneni in the year 1981 as a Private Limited Company to be in the business of Research, Developing, Manufacturing and Marketing of Pharmaceutical Substances and Finished Dosage forms for Indian and International markets."

16. Denied, except to admit that Natco Ltd. does not contest personal jurisdiction within this judicial district for the limited purposes of this action with respect to the '483 Patent.

17. Denied, except to admit that Natco Inc. does not contest personal jurisdiction within this judicial district for the limited purposes of this action with respect to the '483 Patent.

18. Denied, except to admit that Natco Inc. is a wholly owned subsidiary of Natco Ltd.

19. Denied, except to admit that Natco Ltd. filed ANDA No. 202595 with the FDA in order to obtain approval to engage in the commercial manufacture, use or sale of oseltamivir phosphate capsules, 75 mg.

20. Denied, except to admit that Natco Ltd. does not contest personal jurisdiction within this judicial district for the limited purposes of this action with respect to the '483 Patent.

21. Admitted.

22. Denied, except to admit that a February 9, 2011 press release on the Alvogen website at http://www.alvogen.com/NewsMedia/ViewNews/Alvogenandnatcosecurefirsttofile statusongenericversionoftamiflu includes the following statement: "Alvogen, the US-based pharmaceutical company, today announced that its India-based partner, Natco Pharma Limited, has filed an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) for the generic version of Tamiflu® (oseltamivir phosphate)." Further

admitted that a February 9, 2011 press release on the Natco website at http://www.natcopharma.co.in/tamiflu.html is titled: "NATCO files ANDA for Oseltamivir, (Tamiflu®) ties up with Alvogen, gets First to File Status."

23. Denied, except to admit that Natco Ltd. does not contest personal jurisdiction within this judicial district for the limited purposes of this action with respect to the '483 Patent.

24. Denied, except to admit that Natco Inc. is a wholly owned subsidiary of Natco Ltd., and Natco Inc. does not contest personal jurisdiction within this judicial district for the limited purposes of this action with respect to the '483 Patent.

25. Denied.

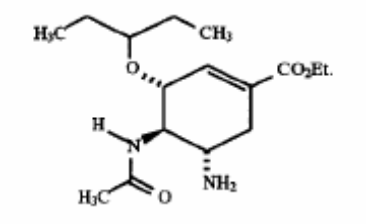
26. Denied, except to admit that Natco does not contest venue within this judicial district for the limited purposes of this action with respect to the '483 Patent.

BACKGROUND

27. Natco is without sufficient knowledge to admit or deny the allegations in Paragraph 27 of the Complaint, and therefore denies the same, leaving Plaintiffs to their proofs, except to admit that Roche is listed in the Orange Book as the Applicant for NDA 21-087 which relates, *inter alia*, to 75 mg capsules of oseltamivir phosphate.

28. Natco is without sufficient knowledge to admit or deny the allegations in Paragraph 28 of the Complaint, and therefore denies the same, leaving Plaintiffs to their proofs, except to admit that the '483 patent on its face is entitled "Carbocyclic Compounds," and the assignee is identified as Gilead Sciences, Inc. Further admitted that the patent issued June 9, 1998, and that a copy is attached as Exhibit A to the Complaint.

29. Denied, except to admit that the '483 patent claims a compound having the following structure:



Further admitted that this compound is the active ingredient in the Tamiflu® product described in NDA No. 21-087, and that Tamiflu® is indicated for the treatment of uncomplicated acute illness due to influenza infection in patients one year and older who have been symptomatic for no more than two days, and for the prophylaxis of influenza in patients one year and older.

30. Natco is without sufficient knowledge to admit or deny the allegations in Paragraph 30 of the Complaint, and therefore denies the same, leaving Plaintiffs to their proofs, except to admit that the '483 patent is listed in the Orange Book for NDA 21-087. Further admitted that according to the Orange Book, the '483 patent expires December 27, 2016, and that the holder of NDA 21-087 obtained a pediatric exclusivity period that expires June 27, 2017.

31. Natco is without sufficient knowledge to admit or deny the allegations in Paragraph 31 of the Complaint, and therefore denies the same, leaving Plaintiffs to their proofs.

32. Natco is without sufficient knowledge to admit or deny the allegations in Paragraph 32 of the Complaint, and therefore denies the same, leaving Plaintiffs to their proofs, except to admit that Natco Ltd. filed ANDA No. 202595 with the FDA in order to obtain approval to engage in the commercial manufacture, use or sale of oseltamivir phosphate capsules, 75 mg.

33. Denied, except to admit that 21 U.S.C. § 355(b)(1) states: "The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such

drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."

34. Natco is without sufficient knowledge to admit or deny the allegations in Paragraph 34 of the Complaint, and therefore denies the same, leaving Plaintiffs to their proofs, except to admit that Roche is listed in the Orange Book as the Applicant for NDA 21-087 which relates, *inter alia,* to 75 mg capsules of oseltamivir phosphate. Further admitted that the '483 patent is listed in the Orange Book for NDA 21-087.

35. Denied, except to admit that 21 U.S.C. § 355(j)(2) states:

(A) An abbreviated application for a new drug shall contain— . . .

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; . . ."

36. Denied, except to admit that 21 U.S.C. § 355(j)(2) states:

(A) An abbreviated application for a new drug shall contain— . . .

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section— . . .

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; . . ."

37. Natco is without sufficient knowledge to admit or deny the allegations in Paragraph 37 of the Complaint, and therefore denies the same, leaving Plaintiffs to their proofs, except to admit that the '483 patent is listed in the Orange Book for NDA 21-087.

38. Denied, except to admit that Natco Ltd. filed ANDA No. 202595 with the FDA in order to obtain approval to engage in the commercial manufacture, use or sale of oseltamivir phosphate capsules, 75 mg. Further admitted that ANDA No. 202595 included a Paragraph IV certification with respect to the '483 patent.

39. Denied, except to admit that Dr. A.K.S. Bhujanga Rao, President-Technical of Natco Pharma Limited sent a letter to Hoffman-La Roche, Inc., Genentech and Gilead Sciences, Inc. on February 2, 2011, whose subject was "Notification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act for U.S. Patent No. 5,763,483 (NDA No. 021087)."

40. Denied, except to admit that Natco Ltd. filed ANDA No. 202595 with the FDA in order to obtain approval to engage in the commercial manufacture, use or sale of oseltamivir phosphate capsules, 75 mg. Further admitted that ANDA No. 202595 included a Paragraph IV certification with respect to the '483 patent.

41. Denied because, *inter alia,* invalid claims cannot be infringed.

Count 1: Infringement under 35 U.S.C. § 271(e)(2)

42. Defendants repeat and incorporate each of the preceding paragraphs 1-41 of this Answer and Counterclaims as if fully set forth herein.

43. Denied, except to admit that Natco Ltd. filed ANDA No. 202595 with the FDA in order to obtain approval to engage in the commercial manufacture, use or sale of oseltamivir phosphate capsules, 75 mg. Further admitted that ANDA No. 202595 included a Paragraph IV certification with respect to the '483 patent.

44. Denied because, *inter alia*, invalid claims cannot be infringed.

45. Denied.

Count 2: Infringement under 35 U.S.C. §§ 271(a),(b) and/or(c)

46. Defendants repeat and incorporate each of the preceding paragraphs 1-45 of this Answer and Counterclaims as if fully set forth herein.

47. Denied, except to admit that Natco Ltd. filed ANDA No. 202595 with the FDA in order to obtain approval to engage in the commercial manufacture, use or sale of oseltamivir phosphate capsules, 75 mg. Further admitted that ANDA No. 202595 included a Paragraph IV certification with respect to the '483 patent.

48. The Court lacks subject matter jurisdiction over the allegations of Paragraph 48 under §§ 271(a),(b) and/or (c), and they are therefore denied.

49. The Court lacks subject matter jurisdiction over the allegations of Paragraph 49 under §§ 271(a),(b) and/or (c), and they are therefore denied.

50. The Court lacks subject matter jurisdiction over the allegations of Paragraph 50 under §§ 271(a),(b) and/or (c), and they are therefore denied.

51. The Court lacks subject matter jurisdiction over the allegations of Paragraph 51 under §§ 271(a),(b) and/or (c), and they are therefore denied.

52. The Court lacks subject matter jurisdiction over the allegations of Paragraph 52 under §§ 271(a),(b) and/or (c), and they are therefore denied.

53. The Court lacks subject matter jurisdiction over the allegations of Paragraph 53 under §§ 271(a),(b) and/or (c), and they are therefore denied.

54. The Court lacks subject matter jurisdiction over the allegations of Paragraph 54 under §§ 271(a),(b) and/or (c), and they are therefore denied.

55. The Court lacks subject matter jurisdiction over the allegations of Paragraph 55 under §§ 271(a),(b) and/or (c), and they are therefore denied.

WHEREFORE, Natco denies that Plaintiffs are entitled to the relief requested in the Complaint.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer and to its ability to seek and allege any and all defenses not presently known or that are revealed during the course of discovery, Natco asserts the following affirmative defenses in response to the Complaint:

First Affirmative Defense

Natco's submission of ANDA No. 202595 does not infringe one or more claims of the '483 patent pursuant to 35 U.S.C. § 271(e).

Second Affirmative Defense

The Court lacks subject matter jurisdiction over allegations relating to 35 U.S.C. §§ 271(a),(b) and/or (c).

Third Affirmative Defense

The claims of the '483 patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including §§ 101, 102, 103, 112, 116 and/or the judicial doctrine barring double-patenting.

Fourth Affirmative Defense

Plaintiffs' Complaint, in whole or in part, fails to state a claim upon which relief can be granted.

COUNTERCLAIMS

For its counterclaims against Gilead Sciences, Inc., Hoffman-La Roche Inc., F. Hoffman-La Roche Ltd. and Genentech, Inc. (collectively "Counterclaim-Defendants"), Natco Pharma Limited and Natco Pharma, Inc. (collectively "Natco") alleges upon knowledge with respect to its own acts, and upon information and belief as to other matters, as follows:

The Parties

1. Natco Pharma Limited is a corporation organized and existing under the laws of India and has a principal place of business at Natco House, Road No. 2, Banjara Hills, Hyderabad – 500 033, India.

2. Natco Pharma Inc. is a Delaware Corporation having a principal place of business at 297 Mine Bank Road, Wellsville, Pennsylvania 17365-9514.

3. On information and belief, Gilead Sciences, Inc. is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 333 Lakeside Drive, Foster City, California 94404.

4. On information and belief, Hoffmann-La Roche Inc. is a company organized and existing under the laws of the State of New Jersey, with its principal place of business at 340 Kingsland Street, Nutley, New Jersey 07110.

5. On information and belief, F. Hoffmann-La Roche Ltd. is a company organized and existing under the laws Switzerland with its principal place of business at CH 4070 Basel, Switzerland.

6. On information and belief, Genentech, Inc. is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 1 DNA Way, South San Francisco, California 94080-4990.

Actual and Justiciable Controversy

7. The United States Patent and Trademark Office issued United States Patent No. 5,763,483 (“the ‘483 Patent”) on June 9, 1998. The face of the ‘483 patent names Gilead Sciences, Inc. as the assignee.

8. On March 15, 2011, Counterclaim-Defendants filed a Complaint alleging, *inter alia*, infringement of the '483 patent by Natco.

9. In their Complaint, Counterclaim-Defendants allege that Natco's submission of Abbreviated New Drug Application ("ANDA") No. 202595 to the Food and Drug Administration ("FDA"), infringes one or more claims of the '483 patent.

10. Natco's submission of ANDA No. 202595 does not infringe one or more claims of the '483 patent.

11. The claims of the '483 patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including §§ 101, 102, 103, 112, 116 and/or the judicial doctrine barring double-patenting.

12. Actual and justiciable controversies exist between Natco and Counterclaim-Defendants relating to the '483 patent.

Jurisdiction and Venue

13. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

14. Personal jurisdiction over the Counterclaim-Defendants exists because the Counterclaim-Defendants have submitted to the personal jurisdiction of the Court.

15. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400 because the Counterclaim-Defendants have submitted to the jurisdiction of the Court.

First Counterclaim (Noninfringement Under 35 U.S.C. § 271(e))

16. Natco repeats and realleges paragraphs 1 – 15 of the counterclaims as if fully set forth herein.

17. Natco's submission of ANDA No. 202595 does not infringe one or more claims of the '483 patent pursuant to 35 U.S.C. § 271(e).

Second Counterclaim (Invalidity)

18. Natco repeats and realleges paragraphs 1 – 17 of the counterclaims as if fully set forth herein.

19. The claims of the '483 patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including §§ 101, 102, 103, 112, 116 and/or the judicial doctrine barring double-patenting.

PRAYER FOR RELIEF

WHEREFORE, Natco respectfully requests this Court to enter judgment for Natco and against Counterclaim-Defendants, and decree:

A. That the Complaint be dismissed with prejudice, and that Counterclaim-Defendants take nothing by their Complaint;

B. That the claims of the '483 patent are not infringed by Natco;

C. That the claims of the '483 patent are invalid;

D. That this is an exceptional case under 35 U.S.C. § 285;

G. That Natco be awarded its costs and attorneys' fees pursuant to 35 U.S.C. § 285, other statutes or rules, or general power of the Court;

H. That the Counterclaim-Defendants, their officers, agents, servants, employees, attorneys, successors and any person who acts in concert or participation with the counterclaim-defendants, be preliminarily and permanently enjoined from using the '483 patent to block, hamper, hinder or obstruct FDA approval of the products described in ANDA No. 202595; and

I. That Natco be awarded such other and further relief as the Court deems just and proper.

Dated: September 30, 2011

Respectfully submitted,

s/ Diane C. Ragosa
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CERTIFICATE OF SERVICE

I hereby certify that on September 30, 2011, I caused a true and correct copy of the attached **NATCO PHARMA LIMITED'S AND NATCO PHARMA, INC.'S ANSWER AND COUNTERCLAIMS** to be served via the ECF system on:

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/s/Matthew S. Murphy
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